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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/778,548 | 02/07/2001 | David M. Lubman | UM-06102 | 5017 |

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EXAMINER

MARSCHER, ARDIN H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1631

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/778,548

Applicant(s)

LUBMAN ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-91 is/are pending in the application.
- 4a) Of the above claim(s) 1-32, 34, 40-44, 50, 55-58, 71 and 83-87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33, 35-39, 45-49, 51-54, 59-70, 72-82 and 88-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-91 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 7
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION
ELECTION RESPONSE

Applicant's election of Species A (embodiments which do not require direct feeding of an output of a previous separating apparatus into a mass spectrometry apparatus) and D in the Paper, filed 10/14/03, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). It is noted that the description of Specie D was clarified in the Examiner Interview of 10/2/03 to be directed to embodiments which do not require a display of a first physical property regarding protein separation separate from mass spectrometry analysis. Claims 33, 35-39, 45-49, 51-54, 59-70, 72-82, and 88-91 are under examination due to reading on the above elected species. The above list of claims under examination differ by one claim number from applicants' list, filed 10/14/03, apparently because applicants did not correct the claim numbering for the renumbering of claims, filed 10/14/03.

TITLE

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is only directed to protein separation and display whereas protein characterization methods are also claimed.

SCOPE OF ENABLEMENT REJECTION

Claims 33, 35, 36, 38, 39, 45-49, 51, 53, and 54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the practice of utilizing isoelectric focusing for obtaining fractions defined by a distinct pH range, does not reasonably provide enablement for generic non-limited pH range fractionation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

It is noted that fractionating the sample is performed in instant claim 33 to produce fractions defined by a pH range. pH fractionation to achieve such sample

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fractions is only instantly described via isoelectric focusing practice. Ion may be utilized for ion fractionation, but is directed to the charge state of the sample molecules and not pH defined. The fractionation into defined pH ranges without isoelectric focusing is not well known in the art and therefore undue experimentation would be required for any other practice for this purpose for pH range fractionation.

VAGUENESS AND INDEFINITENESS

Claims 33, 35-39, 45-49, 51-54, 69, 70, and 80-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33 etc. are vague and indefinite due to containing an abbreviation without a full name therewith, such as HPLC, ESI, or TOF. Clarification via clearer claim wording is requested. Claims which depend from claims 33 etc. directly or indirectly are also included in this rejection due to their dependence.

Claims 39, 53, 70, and 82 contain the phrase "ESI oa TOF" which is vague and indefinite as to what is meant by "oa". Clarification via clearer claim wording is requested.

PRIOR ART

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 59-67, 69, 72-75, 77, 79-81, 88, and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jindal et al. (P/N 6,358,692).

Jindal et al. discloses the automated continuous multi-dimensional selection and analysis of molecules in the title and abstract as is also instantly claimed with results displayed in Figures 6 – 8. Such displaying of results is required in the instant claims. In the SUMMARY OF THE INVENTION section of the reference in columns 3-4 the invention is directed to such methods wherein liquid chromatography is utilized for purification as well as mass spectrometry analysis of the so purified sample, for example, in column 4, lines 41-55. Tandem stages of purification is described in column 14, lines 40-52, which describes the multiple separating apparatus as present in the instant claims. A control device for valve control of samples is depicted in Figures 1-5 of the reference as also required in certain instant claims. Samples which may be purified and analyzed are described in the reference as including peptides (which are small proteins) in column 15, lines 37-57. The methodology of specific coupling of HPLC to Mass spectrometry is cited in column 16, lines 18-32, as an integrated system practice as is also instantly claimed. Chromatography with non-porous media is described specifically in column 16, lines 33-42, as an option with more description of this type of medium in the bridging paragraph between columns 16 and 17.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to select options of chromatography as well as protein options as clearly disclosed species of Jindal et al. which are thus suggested and motivated as species therefore resulting in the practice of the above listed instant claims.

CLAIM OBJECTIONS

Claims 68, 76, 78, 90, and 91 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

INFORMATION DISCLOSURE STATEMENT

Several citations are lined through on the attached PTO-1449 due to lacking a copy as required for consideration in the papers filed with said PTO-1449.

INFORMALITIES

The disclosure is objected to because of the following informalities:

The amended claims, filed 10/14/03, contain several confusing designations of claim numbers due presumably to an unseeable lining through. For example, whenever a "4" was presumably deleted the lining through fell on top of the middle line of the "4" symbol such as in renumbering of claim 24 as filed to claim 25. This also occurred in the claim dependencies. In the future applicants are requested to adjust the amending so that any such number amending is not hidden by the number being amended.

Appropriate correction is required.

No claim is allowed.

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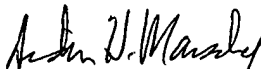
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

December 27, 2003


ARDIN H. MARSCHEL
PRIMARY EXAMINER